DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Re: Zometa
Docket No. 02E-0020

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 4,939,130, filed by Novartis, under 35 U.S.C. § 156 et seq. The Food and Drug Administration (FDA) is technically amending the notice of its determination of the regulatory review period for Zometa that appeared in the *Federal Register* of February 28, 2003 (page 9690), based on information provided in a Request for Revision of Regulatory Review Period (Docket No. 02E-0020 dated and received on May 4, 2005). The notice stated:

> FDA has determined that the applicable regulatory review period for ZOMETA is 2,810 days. Of this time, 2,201 days occurred during the testing phase of the regulatory review period, while 609 days occurred during the approval phase. These periods of time were derived from the following dates:
>
> 1. The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective: December 12, 1993. The applicant claims September 18, 1993, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 12, 1993, which was 30 days after FDA receipt of the IND.

A Request for Revision of Regulatory Review Period was filed for the product on May 4, 2005. FDA reviewed its records and found that the effective date of the investigational new drug application was incorrect due to a clerical error. Therefore, FDA is revising the determination of the regulatory review period to reflect the correct effective date for the investigational new drug application as shown below. The corrected paragraph should now read:

> FDA has determined that the applicable regulatory review period for Zometa is 2,901 days. Of this time, 2,292 days occurred during

the testing phase of the regulatory review period, while 609 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective: September 12, 1993. The applicant claims September 18, 1993, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 12, 1993, which was 30 days after FDA receipt of the IND.

The technical amendment will state in its "Supplementary Information" Section:

1. On page 9690, in the third column, in the first complete paragraph, in line 3 "2,810" is corrected to read "2,901"; in line 4 "2,201" is corrected to read "2,292".
2. On page 9690, in the third column, in the second complete paragraph, in lines 4 and 5, "December 12, 1993" is corrected to read "September 12, 1993"; in line 10, "December 12, 1993"is corrected to read "September 12, 1993."

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Thomas Hoxie
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